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EXAMINER

MCCROSKY, DAVID J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/032,765

Applicant(s)

DRINAN ET AL.

Examiner

David J. McCrosky

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 11 .
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 57-64 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 recites the limitation "the sensor assembly" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 69 recites the limitation "the display device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

Claims 1-13, 15-40, 50-54, 56 and 65-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al in view of Samarati et al. Jacobsen et al teach a method and system for remote monitoring. A biointerface head (14) is attached to the body and transmits data to a control and communication module (18 or 50), which is also attached to the body. Data is continuously transmitted to a data collection unit (320) and/or a remote database management system (400). See col. 4, ll. 33-35. Data transmission is further described and illustrated at col. 15, l. 54 to col. 16, l. 4 and Figs. 7 and 7A. The remote database management system (400) summarizes physiological data by utilizing a flashing icon on a display (col. 14, ll. 41-43) or text/image-based messages to the subject (col. 14, ll. 62-67). Alarms and instructions may be transmitted

to the subject. See col. 11, ll. 41-50. Means for operating a pump or respirator are provided. See col. 9, ll. 42-49 and col. 10, ll. 15-44. Storage means are provided in the data collection unit (320), which collects information from a plurality of control and communication modules (18 or 50) including a user's. See col. 12, ll. 24-33. Jacobsen et al do not teach encryption of the continuously transmitted data. However, Samarati et al teach that data encryption is used for protecting information. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of Jacobsen et al with data encryption, as taught by Samarati et al, to protect information.

Claims 14 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al in view of Samarati et al as applied to claims 1 and 50 above, and further in view of Gowda et al. Jacobsen et al and Samarati et al teach a monitoring system and method as recited for claims 1 and 50. While disclosing non-invasive sensors, the combination does not teach an implantable sensor interface for an invasive sensor. Gowda et al discloses an implantable sensor comprising an external ring, transdermal conduit and a biofluid access port. See abstract. The access port contains a hydrogel filter. See col. 5. A covering encourages cell infiltration. See col. 4, ll. 37-47. Silver prevents bacterial accumulation. See col. 6, ll. 31-36. Gowda et al further teach an external analyte measurement device used in conjunction with the interface. See col. 8, ll. 56-63 and col. 9, ll. 21-30. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of Jacobsen et al and Samarati et al with an implantable interface, as taught by Gowda et

al to provide a more accurate measurement than that provided by a non-invasive sensor.

Claims 41-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al in view of Samarati et al and Simonsen et al. Jacobsen et al teach a method and system for remote monitoring. A biointerface head (14) is attached to the body and transmits data to a control and communication module (18 or 50), which is also attached to the body. Data is continuously transmitted to a data collection unit (320) and/or a remote database management system (400). See col. 4, ll. 33-35. Data transmission is further described and illustrated at col. 15, l. 54 to col. 16, l. 4 and Figs. 7 and 7A. The remote database management system (400) summarizes physiological data by utilizing a flashing icon on a display (col. 14, ll. 41-43) or text/image-based messages to the subject (col. 14, ll. 62-67). Alarms and instructions may be transmitted to the subject. See col. 11, ll. 41-50. Means for operating a pump or respirator are provided. See col. 9, ll. 42-49 and col. 10, ll. 15-44. Storage means are provided in the data collection unit (320), which collects information from a plurality of control and communication modules (18 or 50) including a user's. See col. 12, ll. 24-33. Jacobsen et al do not teach encryption of the continuously transmitted data. However, Samarati et al teach that data encryption is used for protecting information. Jacobsen et al and Samarati et al do not teach repeating the transmission to additional data collection units until communication can be established. Simonsen et al teach a self-organizing network wherein a data collection unit retransmits received information to another data collection unit until the apparatus that the information is meant for receives it. See col.

3, ll. 32-52. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of Jacobsen et al with data encryption, as taught by Samarati et al, and the retransmission means of Simonsen et al to protect information and to ensure receipt of that information.

Claims 50, 51, 56, 65, 66, 72 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flach et al (cited by Applicant) in view of Samarati et al. Flach et al disclose sensors attached to telemeters (102A, 102B), which communicate with more than one VCELL. The VCELLs transmit data to a plurality of monitoring stations. See abstract and col. 6, ll. 24-55. The monitoring station sends control information to the telemeters. See col. 8, ll. 2-5 and col. 19, ll. 4-18. Flach et al do not teach encryption. However, Samarati et al teach that data encryption is used for protecting information. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Flach et al with data encryption, as taught by Samarati et al, to protect information.

#### ***Allowable Subject Matter***

Claims 57-64 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-73 have been considered but are moot in view of the new ground(s) of rejection.

Subsequent to the telephone interview of November 24<sup>th</sup>, Applicant sent a proposed amendment for the Examiner's review. Applicant's proposed amendments were considered. However, the proposed limitation regarding a biointerface head directly attached at a fixed location is no different than the embodiment of claim 14, which is rejected in view of Gowda et al. The proposed data stream limitation is not defined in any way that differs from a conventional definition and doesn't differentiate from the continuous transmission in Jacobsen et al. As such, even if the proposed amendments were incorporated into the claims, the claims would still not define over the prior art.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM

  
ERIC F. WINAKUR  
PRIMARY EXAMINER